### Citation:

Chen L, Appel LJ, Loria C, Lin PH, Champagne CM, Elmer PJ, Ard JD, Mitchell D, Batch BC, Svetkey LP, Caballero B. Reduction in consumption of sugar-sweetened beverages is associated with weight loss: the PREMIER trial. *Am J Clin Nutr*. 2009 May;89(5):1299-306. Epub 2009 Apr 1.

**PubMed ID: 19339405** 

## **Study Design:**

Cohort Study

### Class:

B - Click here for explanation of classification scheme.

## **Research Design and Implementation Rating:**



POSITIVE: See Research Design and Implementation Criteria Checklist below.

## **Research Purpose:**

To examine how changes in beverage consumption affect weight change among adults; the objectives of the current study were to determine:

- how changes in liquid calorie intake affect body weight
- whether liquid calories are more obesogenic than are solid calories
- how changes in consumption of specific beverages affect body weight among adults

#### **Inclusion Criteria:**

- Adults with prehypertension or stage I hypertension (SBP of 120 159 mm Hg and DBP of 80 95 mm Hg)
- Men and women aged 25 79 years

### **Exclusion Criteria:**

- Individuals who used antihypertensive medications, weight loss medications, or oral steroids routinely
- Diabetes
- History of a cardiovascular event
- Congestive heart failure
- Current symptoms of angina or peripheral vascular disease
- Cancer diagnosis or treatment in the past 2 years (except nonmelanoma skin cancer)
- Renal insufficiency
- Psychiatric hospitalization within the past 2 years

# **Description of Study Protocol:**

### Recruitment

Subjects were participants of the PREMIER trial, a completed, 18-month multicenter randomized trial designed to test the blood pressure-lowering effects of 2 multicomponent behavioral interventions in adults with prehypertension or stage I hypertension. Participants were recruited from 4 study centers.

**Design:** Cohort study

Blinding used (if applicable): not applicable

## **Intervention (if applicable)**

Eligible participants were randomized to one of three groups:

- "Advice Only" comparison group that received information but no behavioral counseling on weight loss, increased physical activity, sodium reduction and the DASH dietary pattern
- "Established" behavioral intervention group that received counseling on how to lose weight, increase physical activity, and reduce sodium intake
- "Established Plus DASH" that received counseling on the same lifestyle goals as the Established group along with counseling on the DASH dietary pattern

# **Statistical Analysis**

- Analyses were conducted by combining all participants and adding intervention assignment as a covariate in all models
- For the primary analysis, exposure and outcome variables were modeled as continuous variables
- In sensitivity analyses, the baseline observation carried forward method was used to assess the effect of missing values on study results

# **Data Collection Summary:**

# **Timing of Measurements**

The PREMIER study was conducted from January 2000 through November 2002. Measurements were made at baseline, 6 months and 18 months.

# **Dependent Variables**

- Weight measured with calibrated scale
- Height measured with stadiometer

# **Independent Variables**

- Consumption of sugar-sweetened beverages assessed through 2 multiple pass 24-hour dietary recalls
- Changes in volume, kcal intake, and percentage of calories from beverages both overall and from seven categories (sugar-sweetened beverages (SSBs); diet drinks; milk; 100% juices; coffee and tea with sugar; coffee and tea without sugar or with artificial sweeteners; and alcoholic beverages)
- Solid calorie intake = total calories minus liquid calories

### **Control Variables**

- Fitness
- Physical activity
- Age
- Sex
- Race/ethnicity
- Income
- Education
- Employment
- Marriage status
- Smoking habits
- Intervention assignment

## **Description of Actual Data Sample:**

**Initial N**: all 810 study participants enrolled at baseline were included in the analysis

Attrition (final N): 810 subjects, 61.7% female

**Age**: mean age  $50.0 \pm 8.9$  years

Ethnicity: 34.4% African American, 64.2% non-Hispanic white, 1.4% Others

Other relevant demographics:

**Anthropometrics:** BMI = 33.1 (5.8) kg/m2

**Location**: 4 study centers in the United States (Baltimore, MD; Baton Rouge, LA; Durham, NC; and Portland, OR).

## **Summary of Results:**

## **Key Findings**

- Mean body weight was  $95.2 \pm 1.8$  kg at baseline,  $91.2 \pm 18.9$  kg at 6 months, and  $91.7 \pm 19.7$  kg at 18 months
- Across all groups, mean weight loss was  $3.5 \pm 5.2$  kg at 6 months and  $3.0 \pm 6.1$  kg at 18 months
- Baseline mean intake of liquid calories was 356 kcal/day (19% of total energy intake)
- Of the individual beverages, only intake of SSBs was significantly associated with weight change.
- A reduction in SSB intake of 1 svg/d was associated with a weight loss of 0.49 kg (95% CI: 0.11, 0.82; P = 0.006) at 6 mo and of 0.65 kg (95% CI: 0.22, 1.09; P = 0.003) at 18 mo.
- Participants were divided into tertiles based on their 6- or 18-mo change in consumption of SSBs. At both 6 and 18 mo, participants in the first tertile had a greater mean weight loss than did those in the second (6-mo change: 0.7 kg; P = 0.006; 18-mo change: 1.6 kg; P < 0.001) and third (6-mo change: 2.4 kg; P < 0.001; 18-mo change: 3.6 kg; P < 0.001) tertiles.
- A significant dose-response trend between change in body weight and change in SSB intake was observed at both 6 mo (P < 0.001) and 18 mo (P < 0.001).
- A reduction of 100 kcal per day in liquid calorie intake was associated with a 0.25 kg weight

loss (95% CI: 0.11, 0.39; P < 0.001) at 6 months and of 0.24 kg (95% CI: 0.06, 0.41; P = 0.008) at 18 months; a reduction in solid calorie intake by 100 kcal/day was associated with a 0.06 kg weight loss (95% CI: 0.002, 0.14; P = 0.04) at 6 months and 0.09 kg (95% CI: 0.005, 0.16; P = 0.003) at 18 months.

- Reductions in liquid calorie intake had a stronger effect on weight loss than did a reduction in solid calorie intake, but the difference was statistically significant only at 6 mo (P = 0.006).
- Similarly, a reduction in the percentage of liquid calories from total calories by 1% was associated with a weight loss of 0.04 kg (95% CI: 0.01, 0.06; P = 0.005) at 6 months and of 0.02 kg (95% CI: -0.01, 0.06; P = 0.02) at 18 months.
- When changes in consumption of liquid calories were divided into tertiles, a significant dose-response trend between change in body weight and change in liquid calorie intake was observed for both the 6 month change (P = 0.01) and the 18 month change (P < 0.001).

### **Author Conclusion:**

The authors concluded that their data support recommendations to limit liquid calorie intake among adults and to reduce SSB consumption as a means to accomplish weight loss or avoid excess weight gain.

### Reviewer Comments:

All subjects pooled for analysis. Authors note the following limitations:

- Focus on individuals with prehypertension or stage I hypertension
- Study population contained few Hispanics and Asians

### Research Design and Implementation Criteria Checklist: Primary Research

### **Relevance Questions**

1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)

2. Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?

3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?

4. Is the intervention or procedure feasible? (NA for some epidemiological studies)

### **Validity Questions**

1. Was the research question clearly stated?

Yes

	1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
	1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
	1.3.	Were the target population and setting specified?	Yes
2.	Was the sele	ection of study subjects/patients free from bias?	Yes
	2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
	2.2.	Were criteria applied equally to all study groups?	Yes
	2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
	2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	Were study	groups comparable?	Yes
	3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	???
	3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
	3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
	3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
	3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
	3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method	of handling withdrawals described?	Yes
	4.1.	Were follow-up methods described and the same for all groups?	Yes
	4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes

	4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
	4.4.	Were reasons for withdrawals similar across groups?	N/A
	4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blindin	g used to prevent introduction of bias?	Yes
	5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
	5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
	5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
	5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
	5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.		ention/therapeutic regimens/exposure factor or procedure and ison(s) described in detail? Were interveningfactors described?	Yes
	6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
	6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
	6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
	6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
	6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
	6.6.	Were extra or unplanned treatments described?	N/A
	6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
	6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcom	mes clearly defined and the measurements valid and reliable?	Yes
	7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
	7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes

	7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
	7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
	7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
	7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the stat outcome ind	istical analysis appropriate for the study design and type of icators?	Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	Are conclusi consideratio	ons supported by results with biases and limitations taken into n?	Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due t	o study's funding or sponsorship unlikely?	Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes

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